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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/439889	Shi et al
Examiner	**Group Art Unit**
Ngoc	1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ R sponsive to communication(s) filed on 3/12/02.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-6 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 1-6 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☐ Notice of R ference(s) Cit d, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Acti n Summary

The amendment of 3/12/02 has been entered. The amendment amended claims 1 and 2.

Claims examined on the merits are 1-6 which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the last line of claims 1 and 2, -- pads -- should be inserted after "polymer" to be clear since there is inadequate antecedent basis for a porous polymer that is not in the form of pads.

In line 1 of claim 2, -- freeze-dried -- should be inserted before "porous" since the process steps claimed produce freeze-dried porous polymer pads on a solid support.

Claims 5 and 6 are indefinite for reasons set forth in the previous office action of 3/12/02. The amendment states that claims 5 and 6 have been amended following the Examiner's suggestions. However, claims 5 and 6 have not been amended. Only claims 1 and 2 have been amended.

Claim 5 is unclear by requiring freezing the array on the solid support, and not requiring an initial step of providing the array on the support. It is unclear as to whether freezing is attaching the array to the support or is freezing the array after being attached to the support.

Claim 5 is further unclear by reciting "an array comprising" since the term "array" sets form an arrangement of the porous polymer pads on the support and cannot comprise the porous polymer pads on the support.

To overcome, the above indefiniteness, it suggested that claim 5 be changed to read --

A method for freeze drying an array of porous polymer pads on the surface of a solid support, said method comprising:

a. providing an array of porous polymer pads on the surface of a solid support,

b. freezing said array of porous polymer pads on the surface, and then

C. drying said array of porous polymer pads on the surface at reduced pressure. --.

Claim 6 is unclear by being dependent on claim 5 and requiring steps of being "frozen" and "dried under vacuum to remove water" since claim 5 requires "freezing" and "drying---at reduced pressure". It is suggested that claim 6 by amended by canceling "the porous polymer pads are frozen" in line 1 and inserting -- said freezing is --, and in line 2, canceling "dried under vacuum to remove water" and inserting -- said drying is --.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guschin et al or Khrapko et al (5,552,270) or Chetverin et al (5,616,478) in view of Funk et al (5,973,014), and if necessary in further view of Ruchel (1978) or Ruchel (1975) or Blank et al for reasons set forth in the previous office action of 3/12/02.

The claims are drawn to a method of freeze drying an array of porous polymer pads on a solid support by freezing and drying the array of porous polymer pads on the support at reduced pressure, and to an array of porous polymer pads on a solid support produced by the method.

Guschin et al disclose drying an array of micromatrices of polyacrylamide gel pads on a support for use in immobilizing a compound such as DNA. See the abstract (page 203, left col); the paragraph bridging pages 202 and 204;, page 205, left col, first complete paragraph; page 207, right col under "Microchip Fabrication"; and page 211, left col, under "CONCLUSION".

Khrapko et al (col 4, lines 1-15) and Chetverin et al (col 12, lines 55-62) disclose providing an array of porous polymer gel pads on the surface of a solid support and then drying the array of porous polymer gel pads on the surface. Chetverin et al disclose the polymer gel being lyophilized or dried in vacuo (col 12, lines 58-59).

Funk et al disclose freeze drying swollen, non-porous, hydrophilic polymers to obtain porous, hydrophilic, highly swellable polymers having a desired pore size and pore distribution (col 2, line 58 to col 3, line 10), and which retain their original shape (col 3, lines 7-8). Monomers used to prepare the polymer can be amides of acids such as acrylic acid (col 3, lines 45-51). The amount of water in the swollen polymer being freeze dried can be used to control the pore size of the freeze dried polymer (col 3, lines 16-18).

Ruchel (1978), Ruchel (1975) and Blank et al disclose freeze drying polyacrylamide gels to obtain porous polyacrylamide polymers.

It would have been obvious to carry out the drying of the array of polymer gel pads on the support of Guschin et al or Khrapko et al or Chetverin et al by freeze drying to obtain the function of freeze drying to produce a porous, highly swellable polymer of a controlled desired pore size and pore distribution as disclosed by Funk et al. It would have been expected that freeze drying can be used to increase the pore size since Funk et al disclose using the amount of water in the swollen polymer freeze dried to obtain a desired pore size. The further disclosure of Ruchel (1978), Ruchel (1975) or Blank et al of freeze drying a polymer gel to obtain a porous polymer, if needed, would have further suggested carrying out the drying of Guschin et al, Khrapko et al or Chetverin et al by freeze drying. Ruchel (1978), in particular, discloses that freeze drying produces a sponge like structure without gel matrix shrinkage (page 564, lines 15-18).

Applicant's arguments filed 3/12/02 have been fully considered but they are not persuasive.

It is granted as urged by applicants that Guschin et al, Khrapko et al and Chetverin et al do not disclose freeze drying to increase pore size. However, Guschin et al, Khrapko et al and Chetverin et al disclose drying porous polymer gels, and Chetverin et al even discloses lyophilizing (col 12, lines 58-59) which is freezing drying. Since Funk et al disclose freeze drying a polymer gel to obtain a porous polymer gel having a desired controlled pore size and distribution and the polymer freeze dried is of the type dried by Guschin et al, Khrapko et al or Chetverin et al, it would have been obvious to freeze-dry the polymer gel

of Guschin et al, Khrapko et al or Chetverin et al to obtain the result of a controlled pore size and distribution as suggested by Funk et al.

Applicants assert that Chetverin et al does not disclose an array. However, the present specification (page 5, lines 5-7) states that the technique of U.S. Patent 5,616,478 provide an array of porous polymer pads. In any event, the polymer gel of Chetverin et al is on a solid support and the gel is in a form that can be considered a pad, and it would have been obvious to provide the polymer gel pad of Chetverin et al as an array of porous polymer gel pads when the function of an array is desired since it is conventional and well known in the art to use an array of porous polymer pads for the procedures involving nucleic acid amplification as disclosed by Chetverin et al. It is apparent from the preamble of claim 1 that drying an array of porous polymer pads on a solid support is known. While Chetverin et al disclose not cross-contaminating between different zones, this does not lead away from increasing pore size. Chetverin et al disclose that the pore size can range from about 100 μm to 5 nm (col 6, line 59). It would have been obvious to use the freeze-drying of Funk et al to obtained a desired controlled pore size within this range. A larger pore size within this range would have been an increase over a smaller pore size. Moreover, as compared to other drying methods, freeze-drying would have inherently resulted in a larger pore size since the improvement of the present invention is using freeze-drying in place of known drying techniques.

Applicants urge that Funk et al does not disclose using a liquid nitrogen temperature. However, only claim 6 requires freezing at liquid

nitrogen temperatures. In view of the specification, this appears to require freezing with liquid nitrogen rather than lowering the temperature of the polymer pad to the temperature of liquid nitrogen. As set forth in the paragraph bridging pages 11 and 12 of the specification, the gel pad array is dipped into liquid nitrogen. Merely dipping into liquid nitrogen will not lower the temperature of the gel pad array to the temperature of the liquid nitrogen. In any event, freezing with liquid nitrogen is a well known way of freezing material in carrying out freeze drying, and it would have been obvious to use liquid nitrogen to carry out the freezing of Funk et al and as required by claim 6.

Applicants urge that Funk et al does not teach that increasing pore size will allow macromolecules access to a 3-dimensional polymer matrix. However, such access of macromolecules would have been obvious without a specific disclosure in Funk et al. Obviously, an increase in pore size will allow larger molecules to enter the pores.

Applicants urge that Blank et al and Ruchel (1975) and (1978) do not teach that freeze-drying will increase pore size. However, these references are combined with the Funk et al patent which suggests that freeze-drying can be used to increase pore size.

Applicants urge that there is no motivation to combine Funk et al with Guschin et al, Khrapko et al or Chetverin et al. However, there is clear motivation. The motivation is to obtain in Guschin et al, Khrapko et al or Chetverin et al the function of freeze-drying when used to dry a polymer gel as disclosed by Funk et al, i.e. to obtain the result of producing a dried polymer gel having a controlled pore size and pore

distribution (Funk et al, col 3, lines 15-30). Obviously, controlling pore size and distribution when drying in Guschin et al, Khrapko et al or Chetverin et al would have been expected to an advantage since each reference is drying a porous polymer gel. When a larger pore size is selected, this will be larger than a smaller pore size. Furthermore, when freeze-drying the polymer gel of Guschin et al, Khrapko et al or Chetverin et al, a larger pore size will inherently be obtained as compared to using other methods of drying. In the present invention, the pore size increase is with respect to drying methods other than freeze-drying since the improvement is using freeze-drying in place of known drying methods.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone

number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651

DMN
5/24/02